K131842

5. 510(k) SUMMARY

DATE: August 16, 2013

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Kimberly Smith, Regulatory Affairs Specialist
Phone: (610) 596-2326
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AUG 2 0 2013

DEVICE NAME: Sterican™ Cannula

COMMON NAME: Cannula

DEVICE CLASSIFICATION: 21 CFR §880.5570, Class II
Hypodermic single lumen needle
Classification Product Code: FMI

PREDICATE DEVICE: 510(k) Number: K944931
Device Name: Becton Dickinson Blunt Steel Cannula
Classification Product Code: FMI
Regulation Number: §880.5570, Class II
Applicant: BD Becton Dickinson Vacutainer Systems Preanalytic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION
The Sterican™ Cannula is a semi blunt, 18G (1.20mm) x 1½ inch (40 mm) cannula configuration with a single cut bevel (40°). The hub can be used to establish either slip fit or locking type connections to male 6% (Luer) taper slip fit or locking type adapters.

INDICATIONS FOR USE
The Sterican™ Cannula is intended for the aspiration of fluids for fluid transfer and may be used with a syringe for transferring fluids from stoppered vials, glass or plastic ampoules. The Sterican™ Cannula is intended for drug admixture only.

SUBSTANTIAL EQUIVALENCE
B. Braun Medical Inc's. Sterican™ Cannula is substantially equivalent to the predicate device having similar indications for use, technological properties and performance.

Technical Characteristics
Sterican™ Cannula has similar physical and technical characteristics to the predicate device. Both the Sterican™ Cannula and the predicate device are comprised of a protective cap,

stainless steel cannula and a hub. Both devices are comprised of similar materials and components.

Performance Data

Biocompatibility and performance testing was performed with Sterican™ Cannula to support substantial equivalence to the predicate device. Biocompatibility testing was performed in accordance with ISO 10993-1. Performance testing was performed to demonstrate safety and effectiveness.

CONCLUSION

Based on the results of biocompatibility and performance testing, the proposed B. Braun Medical Sterican™ Cannula is considered substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

B. Braun Medical, Incorporated
Ms. Kimberly Smith
Regulatory Affairs Specialist
901 Marcon Boulevard
ALLENTOWN PA 18109-9341

Re: K131842
Trade/Device Name: Sterican™ Cannula
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 17, 2013
Received: June 21, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -
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Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131842

Device Name: Sterican™ Cannula

Indications For Use:

The Sterican™ Cannula is intended for the aspiration of fluids for fluid transfer and may be used with a syringe for transferring fluids from stoppered vials, glass or plastic ampoules. The Sterican™ Cannula is intended for drug admixture only.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C.
Chapman
2013.09.16
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